> perience that reimbursement for physician administered drugs is typically not a point of negotiation between BCBSMA and physicians. BCBSMA establishes, and periodically updates, fee schedules that govern the amount that any physician or physician organization in the BCBSMA network will be reimbursed both for the physician administered drugs and for the administration fee associated with administration of those drugs to insureds.

(DeVaux Aff. ¶ 7). While she was aware that some physicians or physician groups with large practices who could buy in greater quantities may have paid less, and other doctors may have paid more to acquire these drugs, she was not aware of spreads of more than 30% and did not know that pharmaceutical companies were inflating the AWP to increase their market share for these drugs at the expense of payors. (*Id.* ¶ 16.) She also didn't know which manufacturers were involved in marketing the spread. (*Id.*)

Edward S. Curran, Jr., a key defense witness, worked at BCBSMA from 1988 to 1992 as the Director of Pharmacy. (Curran Aff. ¶ 1.) His primary responsibilities included negotiating with drug manufacturers for rebates payable to BCBSMA in consideration for formulary status in the area of SADs. (*Id.* ¶ 14.) He also negotiated with drug manufacturers for rebates and discounts for use at the staff model HMO sites. (*Id.* ¶ 15.) He was a signatory on these contracts as finalized. He worked closely with the staff model HMO Medical East/West sites and knew that rebates varied widely from drug to drug. (*Id.* ¶ 16.) However, Curran testified he had "no clue" about how physician-administered drugs were purchased by doctors. (11/13/06 Tr. 36:24–37:5 (Curran).) He did not know that pharmaceutical manufacturers were marketing the spread so that doctors could make a profit.

Curran did say he had a role in purchasing PADs for the HMO but has no memory of any specific drugs. According to Maureen Coneys, the Medical East/West HMOs independently contracted with manufacturers to purchase PADs. (Coneys Aff. ¶ 10.) Even though Curran likely had some knowledge of negotiations involving rebates and discounts for PADs at the HMO, which would be attributable to BCBSMA, it was likely of quite limited significance to the AWP issues in this litigation because BCBSMA did not shift to AWP until 1995 *after* he left as Director of Pharmacy in 1992; thus, any knowledge he gained about the rebates available to the HMO sites did not give BCBSMA material information about the spreads between AWP and ASP available to private physicians in the network, or about marketing the spread to individual physicians or physician groups.

The HMOs were sold in 1997, two years after BCBSMA instituted AWP pricing. Therefore, any knowledge about the spread involving AWP gleaned by ongoing communications between the parent and the subsidiary likely existed only for a two year time period. While there is evidence that there were discussions with the parent, there is little evidence that detailed information about spreads was conveyed to the parent.

It is true that other employees (Gary Shramek and John Killion who worked at BCBSMA) knew that AWPs did not reflect acquisition costs, but they did not have detailed information about the size of the spreads until the late 1990's. Gary Shramek, who was employed by BCBSMA as a Pharmacy Program Director from September 1999 to October 2002, became personally familiar with acquisition costs of 60 percent off AWP on PADs because of rebates and discounts from manufacturers

and discussed this information with other BCBSMA employees. (Shramek Aff. ¶ 10.) In June 2002, he learned that U.S. Oncology (a large buyer) could purchase drugs for 18%–40% off AWP which is equivalent to spreads of 22%–67%. (*See* DX 1148 at 17376.) Several other BCBSMA employees also testified that sometime in the mid-to-late 1990's they became aware that AWP was not a true average wholesale price. (*See, e.g.*, Fox Dep. 126:16–127:10 (explaining his understanding that AWP was a "sticker price"); Fanale Dep. 84:13–86:13 (acknowledging that he knew doctors earned a profit on the drugs); Killion Dep. 119:9–22 (stating his knowledge that AWP was an "artificial price").)

BCBSMA had limited knowledge of the spreads by the mid–1990's. (*See, e.g.*, DX 1979 at 30343 (minutes from the 1994 BCBSMA tri-regional carrier Medical Directors meeting stating in regard to a particular drug that BCBSMA "can't rely on Red Book b/c physician's are generating huge profit"); DX 1980 at 30378 (minutes from the May 1996 BCBS Technology Advisory Committee meeting stating that AWP is "grossly inflated").) Beginning in 1999, BCBSMA employees understood that oncologists were generally making big money off of chemotherapy drugs, but BCBSMA was not able to determine the exact discount off of AWP that these oncologists were receiving. (*See* DX 1020 at 0066 ("We are not able to determine the exact discount off of AWP that MASCO is receiving, however, our contacts in the pharmacy business indicate drug companies offer substantial discounts to increase their market share. It appears that the physicians at MASCO are making money off of the drugs (we pay 95% of AWP, they buy the drugs for less), and are threatening to stop administering drugs in their office in order to keep reimbursement up.").) Concerned about holding the "patient hostage," BCBSMA explored different alternatives, like looking at the data as to whether the hospital setting was different and whether another method of purchasing the drugs and shipping them to the doctor should be explored.

I find that at least by 1999, employees at BCBSMA actually understood that AWP was not a real average and that doctors were receiving large discounts. However, for the most part, they still did not have any detailed knowledge on a drug-by-drug basis of the extent of the spreads.

2. Pipefitters: Class 3 Representative

Plaintiff Pipefitters Local 537 Trust Fund ("Pipefitters") is a Class 3 representative. Pipefitters is a Taft–Hartley[29] multi-employer trust fund that provides health and welfare coverage for the local members of the Pipefitters union. Members of the Pipefitters union are tradesmen and tradeswomen who work on building systems. (Hannaford Aff. ¶ 9.) The small staff of the Pipefitters Trust Fund consists of six employees, including the Fund Administrator. (*Id.* ¶ 6.)

The Fund provides major medical benefits, including prescription drug benefits, to all union members and their eligible dependents. (*Id.* ¶ 7.) Currently there are approximately 4,600 individuals, both union members and their dependents, who receive major medical benefits, including prescription drug benefits, through the Pipefitters Fund. (*Id.* ¶ 8.) In general, the

29. A Taft–Hartley fund provides health and welfare benefits for union members. The fund, pursuant to federal law, is "administered jointly by employer-designated trustees and union-designated trustees." *Levy v. Local Union No. 810*, 20 F.3d 516, 517–18 (2d Cir. 1994) (citing 29 U.S.C. § 186(c)(5)(B) (West 1978)).

Pipefitters Fund covers 90 percent of all costs associated with treatment of its members, including the cost of pharmaceuticals. (*Id.* ¶ 10.)

Since approximately 1979, Pipefitters has contracted with BCBSMA to administer major medical benefits, including coverage for all prescription benefits, provided to members. (Hannaford Aff. ¶ 11.) Pipefitters uses this arrangement because it allows the Fund to obtain the "bargaining power" that BCBSMA has with doctors. (11/6/06 Tr. 177:2–5 (Hannaford).) Pipefitters has no ability to negotiate directly with providers and therefore is dependent on BCBSMA for its information on issues relating to prescription drug coverage. (*Id.* 184:5–7.) Pipefitters was aware that BCBSMA contracted to pay providers 95% of AWP for physician administered drugs. (*Id.* 167:11–168:2.)

The financial arrangement between Pipefitters and BCBSMA is "cost plus," meaning that BCBSMA charges Pipefitters whatever it pays for the particular service or pharmaceutical plus an administrative fee. (Hannaford Aff. ¶ 11.) In this way, the Pipefitters Fund is fully responsible for all costs associated with benefits provided to its members. Based on claims data provided from BCBSMA, Pipefitters has paid for drugs manufactured by AstraZeneca, BMS, and J & J. (*Id.* ¶ 12; *see* PX 4012.) In the case of Schering–Plough's multi-source albuterol, Pipefitters has purchased a drug with a J-code matching that of Schering–Plough's products. (*See* PX 4012.) According to Charles Hannaford, the Fund Administrator, Pipefitters was not aware that AWP was not an average price, had no knowledge of any government studies, and did not know about the practice of marketing the spread. (Hannaford Aff. ¶¶ 13, 16).

30. These drugs are Zoladex (AZ), Cytoxan injectable (BMS), Paraplatin (BMS), Rubex (BMS), Taxol (BMS), Procrit (J & J), and albuterol/Proventil (SPW). (PX 4012.)

3. Sheet Metal Workers: Class 2 Representative

Plaintiff Sheet Metal Workers National Health Fund ("Sheet Metal Workers"), a Taft–Hartley multi-employer fund, is a Class 2 representative. Sheet Metal Workers offers a Supplemental Medicare Wraparound Plus program for over 15,000 retirees and covered beneficiaries. In this program, its payments are directly tied to what Medicare pays, covering 20 percent of Medicare's allowable amount. (Randle Rev. Aff. ¶ 4.) Sheet Metal Workers believed AWP was an actual average of prices and did not know of spread marketing or any government studies about the spread. (Faulkner Rev. Aff. ¶¶ 6–14.)

Sheet Metal Workers employs a third-party administrator, Southern Benefits Administrators ("SBA"), to handle claims and to act both as a third-party administrator and as a consultant to advise the Fund on issues relating to healthcare. (11/6/06 Tr. 204:19–22 (Randle).) Sheet Metal Workers has employed SBA since 1996 to negotiate, contract for, and administer health benefits for its active and retired workers. (*Id.* 205:16–206:8.) Sheet Metal Workers relies on SBA to advise it on providing benefits to its members at the best possible price. (*Id.* 207:16–208:3.) Sheet Metal Workers has paid reimbursements for at least one of each of defendants' drugs.[30] (*See* PX 4012.) Plaintiffs have not identified any individual Class 3 members.

M. *Defendants*

1. AstraZeneca

AstraZeneca[31] manufactures and sells Zoladex, an injectable physician-adminis-

31. Defendant "AstraZeneca" collectively in-

tered drug primarily used to treat prostate cancer. (Black Decl. ¶ 9.) Zoladex, the only AstraZeneca drug at issue in this trial, is a medical alternative to surgical castration. Typically, Zoladex is administered by a medical professional in the abdomen once a month or once every three months.

Launched in January 1990, Zoladex has been a single-source drug throughout the class period. Since its launch, however, Zoladex has been in direct competition with Lupron, manufactured by TAP Pharmaceuticals. Lupron is also injected by a physician. Although the method of injection differs, many physicians view Lupron and Zoladex as therapeutically equivalent. (Freeberry Dep. 26:19–27:6.)

AstraZeneca provided a WAC [32] and a corresponding AWP for Zoladex to First DataBank and Redbook. AstraZeneca's suggested AWPs for Zoladex were 25% higher than WAC. This relationship remained constant over the class period. (Gould Decl. ¶ 8; Black Decl. ¶ 16.) AstraZeneca effectively controlled the AWPs for its drugs.

AstraZeneca's pricing decisions for Zoladex were driven by the competitive market for Lupron and Zoladex. At launch, AstraZeneca set the WAC for Zoladex at $255, approximately $75 less per injection than Lupron. (*See* Gould Decl. ¶ 9, Fig. 2.) AstraZeneca periodically increased the WAC for Zoladex, although for some time the company had a policy to keep the average WAC price increase of its products below the rate of inflation. (DX 2119, at AZ0049325; Black Decl. ¶ 5; 11/28/06 Tr. 9:13–21 (Milbauer).) The average annual price increase for Zoladex was 2.6%, whereas the average increase in Lupron was 4.1% over the same time period. (Gould Decl. ¶ 10.) Thus, Lupron always had a higher WAC and AWP than Zoladex. (*See* Gould Decl. ¶ 9, Fig. 2; 12/04/06 Tr. 68:23–69:2 (Gould).) As a result, patients, the Medicare program, and private insurers paid less when Zoladex was administered instead of Lupron. Reimbursement was also less when Medicare Part B carriers used a least costly alternative ("LCA") policy, whereby claims for Lupron and Zoladex were reimbursed based on the AWP for the less costly of the two. (DX 2075 at I.) Since Zoladex had the lower AWP, under the LCA the Zoladex AWP was used for reimbursement of both products.[33] By 1999, the majority of Medicare Part B carriers had implemented a LCA policy. (Rosenthal Decl. ¶ 47.)

From 1990 to 1993, AstraZeneca sold Zoladex directly to physicians and other purchasers at WAC, offering only a standard 2% prompt pay discount. (Milbauer Decl. ¶ 27; DX 2078.) Despite having a lower cost, Zoladex was unable to gain market share from Lupron, the market leader, because the AWP-based reimbursement system created a financial incentive for physicians to choose higher priced products for their Medicare patients. (11/28/06 Tr. 14:1–10 (Milbauer); Milbauer Decl. ¶¶ 29–31; Black Decl. ¶¶ 17–18; 11/14/06 Tr. 11:1–12:8, 36:11–18 (Buckanavage); PX 14 at AZ0237143; PX 119 at AZ0010297.) Physicians could earn more

cludes AstraZeneca Pharmaceuticals L.P., Zeneca, Inc., and AstraZeneca U.S. AstraZeneca Pharmaceuticals L.P. and Zeneca, Inc. are U.S. subsidiaries of AstraZeneca, PLC, a limited liability company domiciled in the United Kingdom. AstraZeneca U.S. maintains its headquarters in Wilmington, Delaware.

32. WAC is sometimes referred to as the list price or catalogue price.

33. Dr. Hartman continues to assess damages after 1999, when the LCA went into effect.

income on Lupron because while both drugs published an AWP that was a 25 percent markup over WAC, 25 percent of a higher price created a larger absolute dollar spread for physicians. AstraZeneca expressed frustration with this dynamic, noting that "[o]ur campaigns to grow ZOLADEX sales based on product attributes and somewhat straightforward pricing strategies have continually been thwarted by TAP response [34] as well as the method used by Medicare to reimburse for LhRh agonists." [35] (PX 14 at AZ0237143.)

AstraZeneca faced a difficult competitive situation: find a way to compete with TAP, or see sales of Zoladex continue to languish. The company believed that "in order to compete in [a] market dominated by Medicare, there needs to be a compelling argument based on 'total return to practice.'" (PX 14 at AZ0237143.) A 1995 Pricing Strategy memo explained:

> Return to Practice is enhanced by widening the margin between the published price and the acquisition cost. This can be accomplished through several pricing manipulations:
>
> 1) Increase the AWP
>
> 2) Decrease the acquisition cost relative to the AWP, or
>
> 3) Both 1 and 2.
>
> In order to maximize the Return to Practice, and to maximize our competitive position, it is recommended that we exercise option # 3 from above....

(PX 133 at AZ0080409; *see also* PX 19 at AZ0021763 (recommending an increase in AWP and additional discounts).) Thus, AstraZeneca chose to begin offering discounts to its physicians, while continuing to make increases in the WAC price and the corresponding published AWP. (*See* PX 4030 at ¶ 40, Fig. 3.) AstraZeneca knew that its AWP was a fictitious and artificial number, (Freeberry Dep. 168:6–20, 172:19–173:8.), but felt no need to correct its reported price because it was standard industry practice to leave the AWP at 25 percent above WAC. (Black Decl. ¶ 16.)

Furthermore, AstraZeneca rationalized that the leveling of the playing field between Zoladex and Lupron resulted in lower costs to patients and the healthcare system when physicians switched to using the lower priced drug, Zoladex. (11/28/06 Tr. 17:13–19 (Milbauer); Gould Decl. ¶ 42–44; Black Decl. ¶ 24.) For example, in 1996 Zoladex was priced $112.60 less per dose than Lupron, saving patients and the healthcare system $22.52 and $90.08 per dose, respectively, if they used Zoladex rather than Lupron. (PX 19 at AZ0021764.) AstraZeneca trumpets this cost savings to Medicare, noting that their economist estimated that the shift in market share between Lupron and Zoladex from 1991 to 2002 saved $129 million in patient co-payments and $516 million in Medicare payments. (Gould Decl. ¶¶ 42–44, fig. 12; 12/04/06 Tr. 100:19–102:21 (Gould).)

The reported AWP for Zoladex, however, was drifting farther and farther away from the actual selling price of the drug. In 1995 the spread rose to over 40% and continued rising steadily to reach over 140% in 2002. (PX 4028.) During that year, the AWP for a 3.6 mg dose of Zola-

34. TAP later pled guilty to conspiring to violate the Prescription Drug Marketing Act, based on conduct during this time period including allegations of encouraging urologists to bill for free samples, inflating AWP to market the spread, and providing kickbacks to doctors who prescribed Lupron rather than Zoladex. (Hartman Decl. ¶ 24, citing MedPAC report.)

35. Both Zoladex and Lupron were LhRh agonists.

dex was $469.99, while the ASP [36] was only $194.62.[37] (*Id.*; Hartman Decl. Attach. G.1.b.)

Despite understanding that patients and payors were paying for Zoladex based upon these inflated AWPs, AstraZeneca seemed unconcerned. Alan Milbauer, AstraZeneca's VP of Public Affairs, acknowledged that "yes, the reimbursements went up, but it was overall less cost to the health care system and less cost to the patient. So I actually felt good about that." (11/28/06 Tr. 26:16–25 (Milbauer).)

In conjunction with increasing the spread, AstraZeneca began marketing Zoladex based upon the return to practice that physicians could earn. (*See* Chen Dep. 126:17–21.) Sales representatives sent a letter to potential accounts encouraging them to switch to Zoladex based on the current AWPs, cost to physicians, and the resulting return to practice in relation to Lupron. (*See* PX 38 at AZ105880.) The letter emphasized that switching to Zoladex "could significantly increase your profits." (*Id.*) A section titled "DO THE MATH!" then explained exactly how to calculate the "Return to Practice." (*Id.*) Zoladex sales representatives provided physicians' offices with information showing "how much money the doctor or office would save purchasing one drug over the other." (Bowman Dep. 57:1–10, 58:2–9.) Sales representatives were also using spreadsheets on their sales calls that demonstrated the spread and compared the "Annual Return to Practice" for Zoladex and Lupron. (*See, e.g.*, PX 33 (email with attached spreadsheet); Bowman Dep. 53:4–14 (discussing charts used to compare return to practice).)

In the course of these actions, there was some concern at AstraZeneca that this spread marketing was crossing over ethical or legal boundaries. In 1996, when AstraZeneca was proposing increasing the WAC and AWP while increasing discounts, an internal memo warned that the "challenge in this instance is to come up with a scenario which ... minimizes any perceived risk from a regulatory/legal/public relations perspective." (DX 2127 at AZ0024480.) Similarly, another pricing strategy memo cautioned that "there is a possible, however likely, risk of a reaction from Medicare. It is feasible that HCFA may see through this strategy and take offense." A 1996 pricing memo even outlined a "justification" for the price increases in the event that there was outside scrutiny:

> [T]he aggressive nature of this price increase may draw some attention, although this is deemed to be unlikely. In the event that our increase is called to task, the move is easily justified on the basis of: 1) increased manufacturing costs, 2) no increase in realized revenue per unit over the last two years, and 3) we are still maintaining our price at a level that is $112.50 less that [sic] our competitor.

36. Plaintiffs' expert, Dr. Hartman, calculates the ASP for each drug NDC using data from the manufacturers. Dr. Hartman includes price reductions and discounts in his calculation of ASP. Hartman's definition of ASP is generally consistent with the definition in the MMA. (*Compare* Hartman Decl. ¶ 3, *with* 42 U.S.C. § 1395w–3a (defining ASP as the manufacturer's total sales divided by the total number of units sold, and including "volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates").)

37. Dr. Hartman recalculated the ASPs for Zoladex, omitting the inclusion of "free goods." (*See* Hartman Rebuttal ¶ 6.) The updated ASPs and resulting spreads are found at PX 4028.

(PX 19 at AZ0021764.) Despite these concerns, AstraZeneca continued to price and market Zoladex based on the return to practice for physicians. (Bowman Dep. 102:12–103:1.) Significantly, AstraZeneca sought to thwart the 1998 Medicare legislation, which reduced reimbursement to 95% of AWP, by increasing the price of Zoladex by 6.9% to "compensate[ ] the customer for this 5% plus provide[ ] an additional improvement in return to practice." (PX 146.)

To its credit, outside of the Medicare system, AstraZeneca attempted to compete with TAP by setting up reimbursement programs that didn't rely on AWP. First, AstraZeneca encouraged health care plans to adopt a maximum allowable cost ("MAC") on Zoladex and Lupron equal to Zoladex's WAC price. (12/04/06 Tr. 17:7–19:13 (Tracy); PX 982D.) The MAC-based reimbursement removed the financial incentive for physicians to purchase the higher priced product. (12/04/06 Tr. 19:2–10 (Tracy); PX 982D; DX 2105.) Second, in 1996 AstraZeneca launched a "Bill to/Ship to" program, which was later renamed the Managed Acquisition Program ("MAP"). (DX 2110; 12/04/06 Tr. 19:20–22 (Tracy); Tracy Decl. ¶ 13; Buckanavage Decl. ¶ 16.) Under the MAP program, managed care organizations would buy Zoladex directly from AstraZeneca at the discount prices, and AstraZeneca would ship Zoladex directly to the physician. (Tracy Decl. ¶¶ 13–14; DX 2110.) This took the physician entirely out of the financial transaction, allowing the health plans to benefit from the discounted prices. In 1999 or 2000, however, AstraZeneca decided not to continue marketing the MAP program because it feared a backlash from physicians. (*See* PX 4024 at AZ04313740; PX 4025 at AZ0431325.)

2. The Johnson & Johnson Group

The "J & J" Defendants include Johnson & Johnson and two wholly-owned subsidiaries, Centocor, Inc. and Ortho Biotech Products, L.P. J & J has two drugs at issue in this case, Procrit and Remicade.

a. *Procrit*

Procrit is the brand name for epoetin alfa, which is used to treat severe anemia, including anemia in AIDS and cancer patients. (Dooley Decl. ¶ 3.) Epoetin alfa is manufactured by Amgen, Inc. and licensed to J & J's Ortho Biotech for sale as Procrit. (11/16/06 Tr. 51:1–9 (Dooley).) Amgen also sells epoetin alfa under the brand name Epogen. Procrit and Epogen are identical, having exactly the same FDA-approved indications for use. (*Id.*) Under an unusual licensing agreement, Amgen has the exclusive right to market epoetin alfa for use in the treatment of anemia in dialysis patients while Ortho Biotech has the exclusive right to market epoetin alfa for non-dialysis uses. (Dooley Decl. ¶ 4.) Physicians, however, are not subject to the terms of the licensing agreement and may lawfully administer either brand of epoetin alfa to any patients they choose. (*Id.* ¶ 5.) Consequently, Procrit and Epogen are sometimes in direct competition with each other.

Ortho Biotech introduced Procrit in January 1991, over a year after Amgen launched Epogen. (*Id.* ¶ 14.) Ortho Biotech set the WAC price and the AWP for most of the Procrit NDCs equal to those already established for Epogen. (*Id.*) The published AWP for Procrit, like that of Epogen, was set 20% higher than the WAC price. (11/16/06 Tr. 57:22–58:3 (Dooley).) After launching Procrit, Ortho Biotech offered discounts below the WAC price to non-dialysis providers in order to encourage physicians to use Procrit rather than Epogen. (*Id.* 58:13–59:2.) These discounts generally ranged from 5% to 10% off of the WAC price, although some high

volume purchasing physicians could receive higher discounts. (Dooley Decl. ¶ 15.) Ortho Biotech also offered rebate programs that ranged between 6% and 12% off of WAC. (11/16/06 Tr. 14:11–15:21 (Dooley).) The WAC price and AWP price remained constant for the six years following Procrit's launch.

J & J fully understood the Medicare reimbursement system and its impact on physician choices. A 1993 memo emphasized that the "goal is to keep the physician 'whole' i.e. whole on the 80% as there is a fear that they will not be reimbursed on the remaining 20%." (PX 339 at 61807.) A 1999 examination of reimbursement scenarios showed that a physician's profit per patient, for a twenty week course of Procrit, could range from a loss of $304 to a gain of $1,520 depending on the percentage of the copayment collected. (PX 346 at 60861.) A 1996 McKinsey & Company consulting report for Ortho Biotech quoted a doctor as stating that "[m]y practice makes $6–8,000 per month on Procrit." (PX 334 at 6790.) The report advised that "[Ortho Biotech] must preserve positive economics for physicians." (PX 334 at 6810.) Significantly, in 1997 when Medicare decided to change Part B reimbursement from 100% of AWP to 95% of AWP, Ortho Biotech responded by making its first price increase since the launch of Procrit. In February of 1997, Ortho Biotech increased the prices on the most popular unit of Procrit by 3.5% and then in January of 1998 increased the prices an additional 1.8%. (PX 237, 238.) The result was that physicians would receive essentially the same reimbursement amount for Procrit after Medicare reduced its reimbursement percentage of AWP.

While J & J worked to "preserve physician economics," there was serious concern at the company that the government would find out about the spreads and take action to reduce the reimbursement amounts. (*See* PX 339 at 61805.) In 1998 Cathleen Dooley, then the Senior Director for Reimbursement and Health Policy, sent an email about Medicare's reimbursement policy for Procrit in which she stated, "[r]ight now they do not know what the cost [of Procrit and Epogen] is for different providers." (PX 259 at 842.) She cautioned that the fact that patients were paying a copayment of a price much higher than the acquisition cost would be a "public relations issue." (*Id.* at 843.) She further noted that the only way that Medicare could determine Procrit's market price was "to require an invoice be submitted with each Medicare claim that is sent in. This would be very cumbersome...." (*Id.* at 842.) Similarly, when Ortho Biotech considered taking a price increase in 1997 and 1998 it was concerned that raising the Procrit AWP above the Epogen AWP could "raise red flags" and "trigger a price survey." (PX 262.) Ortho Biotech recognized that if a survey were taken, "the reimbursement rate would be lowered," which would decrease the profit to providers. (PX 339 at 61805.)

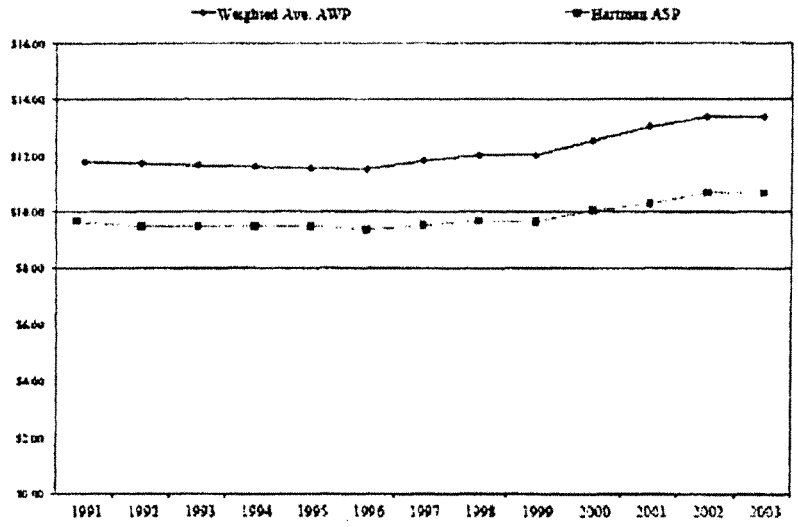
Despite these concerns, J & J actively encouraged their sales representatives to market the spread on Procrit to physicians. The materials for a Sales Training Workshop indicate that one of the training objectives was to "[k]now how to explain PROCRIT Profit to the Pharmacist." (PX 270 at 62599.) Dr. Bell, one of the defendants' experts in this case who previously provided consulting services to Ortho Biotech, advised that the "Procrit sales force must provide compelling evidence that continuing with Procrit provides economic benefits." (PX 344.) He further encouraged Ortho Biotech to develop a spreadsheet that would model those economic benefits of Procrit. (*Id.*)

In at least one region, the sales representatives were receiving specific instructions on ways "to tactfully discuss how an office can profit from providing Procrit in the office." (PX 268 at 63656.) In a 1996 memo to his sales team, Sales Manager John Hess emphasized that the "office needs to understand that there is profit associated with Procrit." (*Id.*) The memo then provides a chart showing a "return on equity for Procrit" and instructing the sales force to "ask for their real numbers" when "reviewing with a physician or office manager." (*Id.*) The memo also specifically quantifies the profits per patient for Medicare and non-Medicare patients over various time periods. (*Id.* at 63657.) Mr. Hess also directed the sales representatives to be discreet in their use of the profit information, instructing them to "simply draw out the scenario on a piece of scratch paper asking for the office billing fee, injection fee, and acquisition fee based on medicare or non-medicare." (*Id.*) The memo closes with an underlined directive: "Do not distribute this memo to your offices. This is for your information only!" (*Id.*)

The main Ortho Biotech office was also highlighting profit potential to physicians in a slide presentation created by an outside company. (*See* PX 331.) One slide asks, "Can you make money? ? ? ?," and the next slide responds, "[d]rugs have paid well under part B." (*Id.* at 1833.) Another slide explains the Medicare reimbursement at 95% of AWP and quotes the current AWP for Procrit. (*Id.* at 1839.) The presentation concludes with the question "Should you give Procrit?" and the first reason supporting an affirmative answer is "Additional revenue." (*Id.* at 1838.) Later in the class period, Ortho Biotech apparently instituted a policy prohibiting spread marketing. A November 2001 memo to the sales force states: "It is absolutely inappropriate to sell product based upon the difference between AWP and acquisition cost." (DX 2767.)

Somewhat surprisingly, given J & J's demonstrated focus on physician profit, the actual spread between the Procrit ASP and the published AWP never exceeded 30% during the class period. (*See* Hartman Decl., Attach. G.3.c and I.3.) While it seems plausible that this would be a result of having only a 20 percent (rather than 25 percent) standard AWP markup over WAC, Dr. Hartman's calculations show that 91 of the 114 spreads for Procrit were actually less than 25%. (*Id.*) Even Dr. Rosenthal concedes that using Hartman's theory of market expectations, Procrit is one of the drugs that AWP seems to work well for because the AWP tracks the ASP. (11/27/06 Tr. 69:21–71:6. (Rosenthal).)

Procrit: ASP vs. AWP
(All NDCs)



(J & J Post–Trial Mem. 6.)

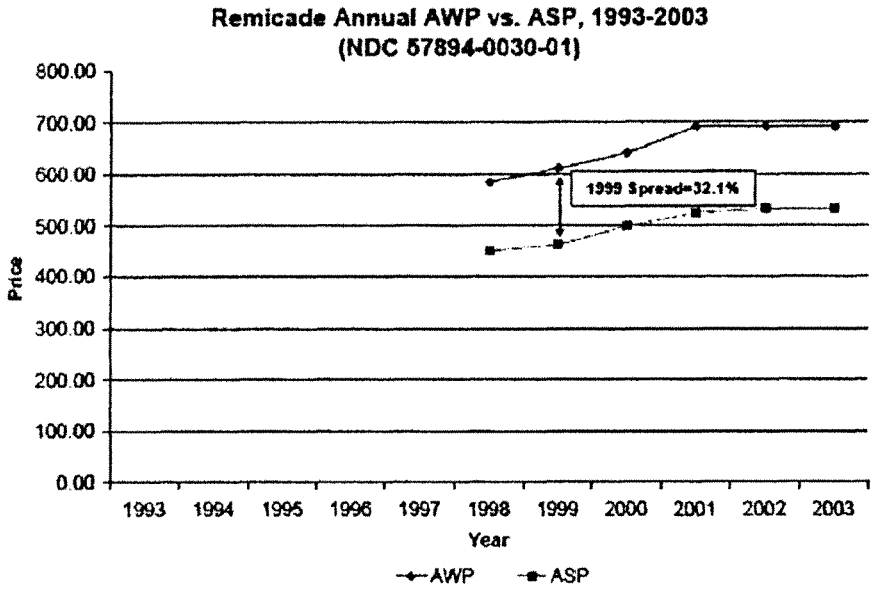
b. *Remicade*

Centocor, Inc. launched Remicade in 1998 and Johnson & Johnson acquired Centocor in 1999. Remicade (infliximab) is used to treat rheumatoid arthritis, Crohn's disease, and other conditions. (11/14/06 Tr. 53:10–16 (Hoffman).) Remicade is administered to patients via intravenous infusion, which frequently takes place in a physician's office, but which may also take place in hospital out-patient departments. Remicade has been a single-source drug from its inception in 1998 and throughout the class period, although it faces therapeutic competition in the treatment of rheumatoid arthritis. (*Id.* 54:8–10.)

Unlike the standard 20 to 25 percent markups in the industry, Centocor set the AWP for Remicade at a 30 percent mark-up over its WAC price. John Hoffman, Vice President of the strategic customer franchise at Centocor, explained why the 30 percent markup was chosen: "It was a combination of looking at what the payors would bear in terms of the price of the product; and . . . that it was going to be financially viable for [physicians] to be able to offer this service and not lose money." (11/14/06 Tr. 56:12–58:25 (Hoffman).) He added that Centocor looked at the spreads between acquisition cost and AWP for other drugs in the same biological class and "picked something that we thought was at the reasonable, the low to middle range of that survey." (*Id.* 58:18–25.) Throughout the class period, Centocor maintained this 30 percent difference between WAC and AWP. (*Id.* 55:20–23.)

Centocor was also unusual in that it did not offer discounts or rebates to physicians. (*Id.* 63, 88–89, 112–15; 11/27/06 77 (Rosenthal).) Centocor sold to specialty distributors, who in turn sold to physicians. The specialty distributors were entitled to prompt pay discounts of up to 2% and other small rebates, and thus upon resale the physicians could only purchase

Remicade at or about the published WAC price. (11/14/06 Tr. 59–61 (Hoffman).) Consequently, the spreads for Remicade hovered very near to 30% throughout the class period. According to Dr. Hartman's calculations, in only two years did the Remicade spreads exceed his 30% expectations yardstick: a spread of 32.1% in 1999 and a spread of 31.9% in 2001. (Hartman Decl., Attach. G.3.c.) J & J disputes these percentages, arguing that Dr. Hartman should have used a weighted average AWP rather than the June 30 AWP to determine the spread. Using their weighted averages, the spread is 30% or less for all years. (Dukes Decl. ¶ 28.)



(Hartman Decl. ¶ 60, Fig. 9.)

Nevertheless, Centocor pursued a strategy of marketing the spread to physicians. Centocor developed and implemented a Practice Management Program ("PMP") to educate physicians on buying, infusing, and billing for Remicade. (Glassco Dep. 20:14–21:22; McHugh Dep. 252:15–253:14.) One of the PMP materials was a "Financial Impact Worksheet," which listed the AWP and allowed the physician to fill in her acquisition cost, the percentage discount off AWP for reimbursement, her case load, and the number of vials per patient. (PX 252 at 3485.) The worksheet then showed the physician how to calculate an "Estimated margin per vial," "Estimated revenue per patient," and "Estimated monthly revenue from REMICADE." (*Id.*) According to John Hoffman, a reimbursement specialist from Centocor would go over this worksheet with physicians and discuss the "financial ramifications" of using Remicade. (11/14/06 Tr. 67:4–7, 68:8–12 (Hoffman).)

Centocor also hosted PMP seminars, where sales representatives made presentations to groups of physicians explaining the profit potential of using Remicade given the AWPbased reimbursement. Senior Sales Executive Laura Glassco explained how she walked doctors through a PowerPoint presentation that illustrated the profitability:

> Basically I would share with the physician ... that AWP was at that time the price that's shown here, [and] that Medicare reimbursement was AWP less 5.... I then walked through with them the scenario which you see here of an example of a patient that might be a three-vial infused patient.... [I]f the cost of the drug was a certain amount, I show the cost of the drug to the physician and I compare that to what the reimbursement was from Medicare.... The last slide shows then the difference between what the physician paid for the drug and what the physician ... gets reimbursed from ... the Medicare carrier.

(Glassco Dep. 105:22–107:21.) The concluding slide showed that, assuming the drug is purchased at list price, the annual profit per patient on Remicade would be $2,293.41. (PX 254 at 90300.)

Laura Glassco also forwarded an email to her sales team, in which she praised one of the sales representatives for his "work in the field." (PX 272 at 90283.) In the forwarded email, the sales representative writes about how he explained reimbursement to the physician and walked through a "Medicare AWP example" showing the potential reimbursement. (*Id.*) He notes that "Dr. Kassan seemed so excited about getting started...." (*Id.*)

3. The Bristol–Myers Squibb Group

The "BMS Group" of defendants is comprised of Bristol–Myers Squibb Co., Oncology Therapeutics Network Corp. ("OTN"), and Apothecon, Inc.[38] BMS is a major developer, manufacturer and marketer of "brand-name" prescription drugs. BMS has seven oncology drugs at issue in this case: Blenoxane, Cytoxan, Etopophos, Paraplatin, Rubex, Taxol, and Vepesid.

OTN is a specialty distributor that sells and distributes injectable drugs and supplies to medical providers who administer them in a hospital or office setting to patients. (Akscin Decl. ¶ 3.) OTN was a joint venture between BMS and another company until 1996 when BMS acquired OTN as a wholly-owned subsidiary.[39] (*Id.* ¶ 2.) OTN's target customers are oncologists in private practice who administer chemotherapy to patients in their offices, rather than oncologists employed by a hospital or hospital out-patient clinic. (Peterson Decl. ¶ 5.)

As the sales agent for BMS oncology products and its wholly-owned subsidiary, OTN had a close relationship with BMS. (*See* Marré Dep. 26:8–20 (referring to the close cooperation using the phrase "One BMS").) For example, OTN customers were able to obtain a four percent discount on BMS oncology products, a discount that was not offered through any other distributor. (12/8/06 Tr. 93:24–94:8 (Peterson).) BMS also established "floor" prices, or minimum prices, for BMS drugs sold by OTN. (Marré Aff. ¶ 6.) BMS's Director of Marketing, Christof Marré, was in weekly contact with OTN to discuss the proper "floor" price and to coordinate joint marketing programs. (Marré Aff. ¶ 7; Marré Dep. 25:11–26:7.) OTN and BMS sales representatives communicated regularly, and OTN Territory Business Development Managers occasionally went on sales calls with their BMS counterparts as part of a strategy commonly referred to within the company as "BMS/OTN Synergy." (Pe-

38. Apothecon was a BMS subsidiary that manufactured and sold primarily generic drugs. BMS sold Apothecon's assets in 2000. There are no Apothecon drugs at issue in this case.

39. On May 11, 2005, after the end of the class period, OTN became an independent, privately-held company. (Akscin Decl. ¶ 2.)

terson Dep. 104:2–105:22; *see* PX 843; PX 228 at 001483222.)

BMS claims to be unique among the defendants because it has never actually reported an AWP or a suggested AWP to the industry publications. (Kaszuba Aff. ¶ 6.) Rather, BMS only reports its wholesale list price, WLP.[40] (Rogers Aff. ¶¶ 1–4; Szabo Aff. ¶¶ 6–7.) The publications then routinely apply a markup factor of 20.5 percent or 25 percent to BMS's WLP to calculate the published AWP. (11/13/06 Tr. 59, 120–21 (Kaszuba); DX 2611 at 6646, 6649.)

While BMS knew that its WLP would be marked up by 20 or 25 percent, BMS did not completely control the AWP percentage markup of its drugs. For example, in 1992, BMS wrote a letter instructing the publishers to change their practice and use a 25 percent markup factor for BMS oncology products. (*See* PX 183.) According to Ms. Kaszuba, this was because Bristol–Myers and Squibb had recently merged, and the publications were using different markup factors depending on whether the drug was a Bristol–Myers or Squibb drug. (Kaszuba Aff. ¶¶ 12–13.) She emphasized that this was the only time that BMS ever directly asked a publication to change the markup factor. (*Id.* ¶ 14.) The success of this request varied by the publisher. Red Book agreed to the change, while First DataBank and Medispan did not. (Kaszuba Aff. ¶ 13.; Szabo Aff. ¶ 6; DX 2554; DX 2650.)

BMS contends that this was an anomalous situation, and that BMS has never had any control over the publications. BMS points to several internal documents which repeatedly emphasize that "BMS does not set AWPs for its products. Third parties set AWP...." (DX 2545; *see* DX 2554; DX 2585 at 0398; DX 2595 at 9757; DX 2587 at 2095; DX 2588 at 9782; DX 2589 at 8211.) Furthermore, documents show that at least one time First DataBank independently changed the markup factor on BMS drugs. (DX 2588 at 9782; DX 2589 at 8206.)

Nevertheless, as a matter of industry practice, BMS knew, expected, and intended that when it reported a price, the publications would predictably calculate an AWP that was 20 to 25 percent higher than WLP. (Marré Aff. ¶ 10; 11/13/06 Tr. 55, 59 (Kaszuba); DX 2611 at 649; DX 2616; Szabo Aff. ¶ 6.) Frank Pasqualone, Senior VP of the Oncology Division, confirmed that the only possible issue was whether the WLP was going to be marked up by 20 or 25 percent. (12/06/06 Tr. 13:5–7 (Pasqualone).) Internal BMS documents show first the list price that BMS was establishing for specific Apothecon drugs and then its "Anticipated AWP" based on the 25 percent markup factor being used at the time. (PX 209; PX 210; PX 211.)

BMS was actively involved with approving the AWP before publication. In a 1998 fax announcing a price change for certain BMS drugs, BMS wrote, "Please supply AWP's for these products once the information has been processed through your database." (PX 179 at 2173.) The publishers would then respond to BMS with a report showing the AWPs so that BMS could "review [the] AWP's for reasonability" before publication. (PX 180 at 6649; *see also* PX 849 (Red Book product listing verification of BMS prices with BMS employee's approval signature).) Denise Kaszuba, Associate Manager of Pricing Support, explained that a BMS employee would be "mathematically ... looking at the AWP to make sure that it is within [the publication's] factor." (11/13/06 Tr. 95:18–96:4 (Kaszuba).) If the AWP was

40. WLP is essentially the BMS term for WAC. (*See* Hartman Decl. ¶ 44.)

different than expected by BMS, Ms. Kaszuba indicated that BMS would contact the publisher. (*Id.* 97:3–10.) All of this is sufficient to conclude that BMS could affect, and at times fully control, the AWP for its drugs.

BMS sells its oncology drugs to customers through intermediary wholesalers. BMS distributes the drugs to wholesalers, who pay WLP for the products. (PX 196 at 8200.) Many large providers contract with BMS to then purchase the drugs from the wholesalers. (Marré Aff. ¶ 6.) The wholesaler provides the product at the contract price and then issues a "charge-back" request to BMS for the difference between WLP and the contract price that the wholesaler collected from the purchaser. (11/14/06 Tr. 155–57 (Marré); *see also* PX 2591 at 6967 (graphic illustration of chargeback process).)

BMS used a similar business model in pricing all of the drugs at issue in this case. The pricing was dependent upon whether a drug was single-source with no competition, single-source with therapeutic competition, or multi-source facing generic competition. At launch, BMS set an initial list price, WLP, for sales to wholesalers. (Pasqualone. Aff.¶ 13.) Wholesalers were generally entitled to a possible 2% prompt pay discount. (*Id.*) BMS would sometimes provide a 5%–10% discount immediately after launch to help get the new product into the marketplace. (*Id.*) Otherwise, there were few discounts, rebates, or price concessions while a drug faced no therapeutic competition. (*Id.* ¶ 16.) During the patent period, BMS would take periodic list price increases "in recognition of prevailing market conditions." (Bell BMS Aff. ¶ 26.) The AWP would rise in step with the WLP increases, so the spread would remain fairly constant throughout the period of patent protection.

Once competition was introduced, BMS would offer discounts and rebates in order to compete with the new alternatives. (Pasqualone ¶ 17.) Marré testified that "the average contract prices and floor prices for BMS drugs in the multi-source portfolio tended to trend down over the long term." (Marré Aff. ¶ 9.) While these actual sales prices were falling, BMS kept the WLP the same as it was before the introduction of competition. (Pasqualone Aff. ¶ 18.) According to BMS employees, BMS did not decrease the list prices of drugs that became multi-source because there were still customers who were willing to pay that list price. (*Id.* ¶¶ 18–19.) Marré explained that some of these customers were just brand loyal, (id.), others lacked information about the discounts, (11/14/06 Tr. 130:9–131:12 (Marré)), and others were not entitled to discounts because they did not have contracts with BMS. (11/14/06 Tr. 159–164 (Marré).) As Dr. Bell notes, given these circumstances it would be economically irrational for BMS to lower its list price to wholesalers because "BMS would be losing revenues." (Bell BMS Aff. ¶ 25.) Thus, the spreads increased over time as the drugs faced more and more competition, and simultaneously fewer and fewer sales were made at or near the list price.

BMS recognized that reimbursement was very important to physicians working in office-based oncology practices ("OBOs"). John Akscin, a Vice President at OTN, acknowledged that OBO revenue is highly Medicare driven because 50 to 55 percent of OBO patients are Medicare recipients. (Akscin Dep. 91–92.) He also noted that 64 percent of OBO revenues came from drug reimbursements. (*Id.* 93; *see also* PX 197 at 6634.) In a presentation to OTN and BMS sales representatives, Mr. Akscin displayed a slide which proclaimed that the "Top Three OBO Concerns" were "Reimbursement, Today,"

"Reimbursement, Tomorrow," and "Reimbursement!" (PX 197 at 6636.) BMS noted the impact of the spreads in a memo concerning the launch of Etopophos:

> Currently, physician practices can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price [AWP]) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physicians' financial incentive for selecting the brand is largely diminished.

(PX 208 at 1221.)

With these financial incentives behind reimbursement, it is easy to see the temptation to market the spread to physicians. BMS, however, had a clear policy against such conduct. In January of 2001, BMS sent a memo to all U.S. Sales & Marketing Personnel advising that, "in accordance with its Code of Conduct, ... the spread should not be used as a promotional or marketing tool." (PX 223.) When asked whether that policy was enforced at BMS, Frank Pasqualone, the Senior VP of the Oncology Division, responded, "Absolutely." (12/06/06 Tr. 15:14–15 (Pasqualone).)

Nevertheless, plaintiffs presented substantial evidence suggesting that BMS was marketing the spread. While I will address drug-specific spread marketing below, there is one significant piece of spread marketing evidence that applies to all the BMS drugs at issue here. OTN offered customers an online "Cost Differential" report for BMS drugs. (*See* PX 219.) The site prompted the customer to input a variety of information, including their AWP reimbursement percentage. The site would then display, by regimen, the reimbursement rate, acquisition cost, and "AWP Cost Differential" (equivalent to the spread) for the requested drugs. (*Id.* at 134–36.)

BMS was well aware that AWP was used as a reimbursement mechanism both under Medicare Part B and through private reimbursement plans. (*See* Marré Aff. ¶ 12; 11/13/06 Tr. 62–64 (Kaszuba); Akscin Dep. 26–27; Peterson Dep. 114–15.) BMS also knew that AWP was an "artificially inflated number." (PX 195.) Yet despite these understandings, there was very little concern, if any, about payors and cancer patients overpaying for their drugs. Sales Representative Douglas Soule best summed up the attitude of BMS when he said, "it's just the system." (12/08/06 Tr. 71:3 (Soule).) When asked if it ever bothered him that people were paying a percentage of a phony price, he finally responded, "No." (*Id.* 71:10.)

In order to examine the selling and pricing of each drug, it is useful to group the BMS drugs into categories depending upon the type of competition that they faced. Two of the BMS drugs, Paraplatin [41] and Etopophos, were patent-protected, single-source drugs for the entire class period. Four drugs, Taxol, Vepesid, Cytoxan tablets, and Blenoxane, all began as single-source drugs and became subject to generic competition at some point during the class period. Finally, Rubex was a branded multi-source drug for the duration of the class period.

a. *Single-source Drugs*

i. *Paraplatin*

BMS launched Paraplatin (carboplatin) in 1989 as a second-generation product to first-generation Platinol (cisplatin). (Bell

41. Paraplatin became subject to generic competition in November 2004 after the class period ended. (Bell BMS Aff. § 13.)

BMS Aff. ¶ 13.) Paraplatin is typically used in the treatment of non-small-cell lung cancer (NSCLC), small-cell lung cancer (SCLC), and ovarian cancer. (*Id.*)

As expected with a single-source drug, there were few discounts given and thus the spreads were fairly close to Dr. Hartman's 30% expectations yardstick. The majority of spreads were under 30%, though the spreads for a few NDCs rose as high as 40%–60% in the years 1997–2002. (*See* Hartman Decl., Attach. G.2.c.) Averaging across all NDCs, however, the overwhelming number of sales were made within 5% of the list price: for all NDCs across all years of the class period, 94.7% of sales were within 5% of the list price. (Bell BMS Aff. Exh. E.)

Paraplatin was often used in combination with Taxol, so BMS often marketed the two products together. Documents suggest that BMS marketed the spread on both drugs. Sales representatives received a presentation entitled "Practice Efficiencies & Quality Care Workshop" that provides revenue and expense information, including a display of the costs and reimbursement amounts for Taxol and Paraplatin. (PX 222.) Each drug had a slide that conveniently listed its AWP, the Medicare allowable percentage, and the OTN cost to the physician. (*Id.* at 2315–16.) Although it was an internal presentation, BMS sales representative Greg Keighley testified that it "was a stand-alone presentation that we would verbally give on an account." (Keighley Dep. 270:2–4.) Keighley used the information in this way on "one or two instances." (*Id.* 270:18–20.) In several pages of call notes from 1998 through 2002, BMS sales representatives detailed their discussions with physicians about reimbursement for Paraplatin and Taxol. For example, in 1998 a sales representative noted that she "[w]ent over some numbers re reimbursement for Taxol/Carbo vs VP/Cis for NSCLC. He agrees that the [Taxol] is better & you do make . . . ." (PX 229 at 4123.) In 1999 another representative noted that he had "gone over AWP numbers & fact that do make money on Taxol/Carbo. . . ." (*Id.* at 8993.) In 2000, one wrote, "Jo is not aware of the . . . value proposition on Paraplatin, so I covered all of this with her." (*Id.* at 3009.) Similarly, in 2002, a representative wrote that he "talked about benefit for reimbursement for taxol + paraplatin regimen over non generic products." (*Id.* at 2251.)

ii. *Etopophos*

Etopophos (etoposide phosphate) was launched in 1996 as the second generation of Vepesid, a product discussed below that had become subject to generic competition in 1994. (Bell BMS Aff. ¶ 14.) Etopophos is typically used in the treatment of SCLC and testicular cancer. (*Id.*) To treat these conditions, Etopophos is generally used in combination with one of the BMS platinum-based oncolytics, Platinol or Paraplatin. The primary advantage of Etopophos over Vepesid is that Etopophos can be administered to the patient much more quickly. (Pasqualone Aff. ¶ 30.)

As with Paraplatin, BMS offered few price concessions for Etopophos. (Bell BMS Aff. ¶ 40.) At its launch in 1996, OTN developed a buy-in program to increase awareness and initial trial usage of Etopophos. (*Id.* ¶ 39.) Presumably, that is why the only Etopophos spread that exceeds 30% occurs in 1996, a 35.8% spread. (*See* Hartman Decl. Attach. G.2.c.) For all other years, the spreads were well below 30% and 100% of sales were made within 5% of the list price. (*Id.*; Bell BMS Aff. Exh. E.)

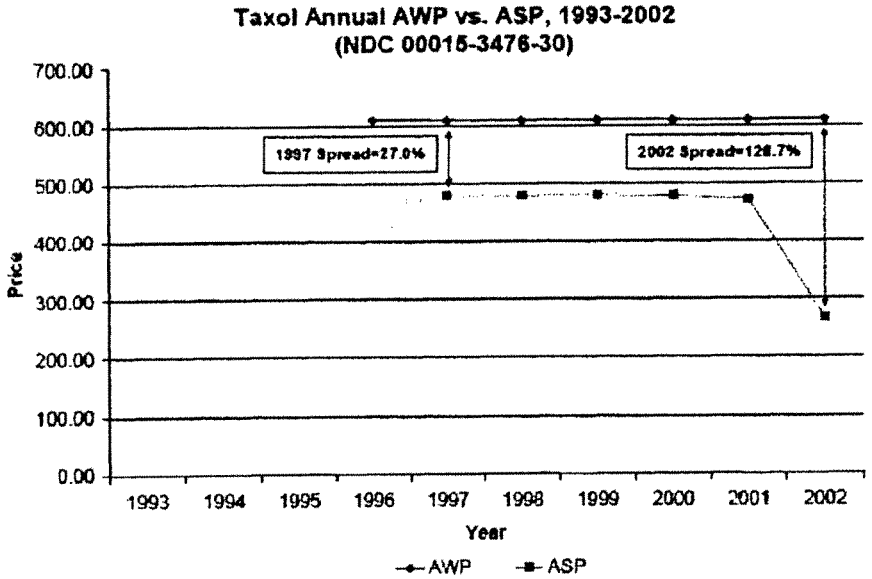
Plaintiffs presented no evidence that BMS specifically marketed the spread on Etopophos.

b. *Single–Source Drugs Later Subject to Generic Competition*

i. *Taxol*

Taxol (paclitaxel) was launched in 1992 and became subject to therapeutic competition in 2000 and generic competition in 2001. (Marré Aff. ¶ 5; Hartman Decl. ¶ 48.) Taxol was the first of a class of agents called taxanes that interrupt the cell cycle of a cancer cell growth stage and make the tumor more susceptible to the effects of radiation. Taxol is used alone or in combination with other products, most often for the treatment of breast cancer, NSCLC, and ovarian cancer. (Bell BMS Aff. ¶ 15.)

Unlike the other single-source drugs, BMS never increased the list price of Taxol. (*Id.* ¶ 42.) During the patent protected period, BMS offered few discounts and the spreads for Taxol were all under 30%. (*See* Hartman Decl. Attach. G.2.c.) Similarly, over 99% of sales were made within 5% of the WLP. (*See* Bell BMS Aff. Exh. E.) When generic entry loomed in 2000, however, BMS had to prepare a strategy to deal with the new low-priced competition. BMS decided to divide the market into three segments, each with its own marketing program: (1) accounts willing to pay a premium for Taxol, (2) accounts that preferred Taxol but were not willing to pay a premium, and (3) accounts that had switched to generic paclitaxel. (Bell BMS Aff. ¶¶ 45–46.) According to Dr. Bell, "[t]his segmentation allowed BMS and OTN to effectively charge a premium to customers who placed the highest value on Taxol and offer lower prices to more price-sensitive customers." (Bell BMS Aff. ¶ 46.) Thus, actual sales prices began to plummet and the spread began to rise. In 2001, the ASP to providers for Taxol dropped by 25%–50%. (Hartman Decl. ¶ 48.) By 2002 the spreads for certain Taxol NDCs were over 500%. (*See* Hartman Decl. Attach G.2.c.) By the fourth quarter of 2002, BMS was routinely providing large discounts on Taxol to high volume customers, some as high as 80% off of WLP. (*See* PX 203 at 6988; PX 204 at 6293; PX 205; PX 206 at 9756.) The result was that in 2002, hardly anyone was paying the list price. Less than 0.5% of sales of Taxol were within 5% of WLP and over 46% of sales were made at a price less than half of WLP. (*See* Bell BMS Aff. Exh. E.)



(Hartman Decl. ¶ 49, Fig. 5.)

BMS carefully educated its sales force on the reimbursement system, the existence of the spread, and the subsequent profitability for a doctor administering Taxol. For example, BMS distributed to its sales force a document entitled "Taxane Economics." (*See* PX 221.) The document presents in detail the costs, reimbursements, and spreads for Taxol and Aventis's Taxotere for different administration periods. (*Id.*) The document indicates that it "should not be utilized in any sales presentations," and there is no evidence that it ever was. (*Id.* at 423.) Sales representatives also received a presentation entitled "Practice Efficiencies & Quality Care Workshop" that provided revenue and expense information, including a display of the costs and reimbursement amounts for Taxol and Paraplatin. (PX 222.) Each drug had a slide that conveniently listed its AWP, the Medicare allowable percentage, and the OTN cost to the physician. (*Id.* at 2315–16.) As discussed above, this document was actually given to customers on at least a couple of occasions. (*See* Keighley Dep. 270:2–22.) Finally, BMS produced a series of sales documents that carefully calculate and illustrate the "profit to oncology practice" of using Taxol or a generic version. (*See* PX 225 at 8052.) Sales representatives were therefore fully prepared to discuss the spread and profitability.

There is substantial evidence that BMS marketed the spread on Taxol. As noted above, Taxol and Paraplatin were often marketed in combination. Thus, many of the sales representatives' call notes cited in the section on Paraplatin also apply here. In addition, several other call notes focus specifically on Taxol. In 1998, a sales representative noted that he "[g]ot info on [Taxol] vs. [Taxotere] w. respect to AWC and AWPs. Also what medicare is reimbursing." (PX 229 at 3600.) In some cases, it is clear that the sales representatives were responding to questions or concerns from the physicians. For example, a 1999 call note states, "message . . . loud and clear. Bottom line, he wants us to raise our AWP or lower our price. I told

him that our AWP is about 25% over acquisition cost, and that we are one of the best in terms of AWP." (*Id.* at 6365.) Another call note reads: "Also said they are considering moving away from TAXOL due to cost issues and reimbursement. Talked about TAXOL going Generic and the advantages this will have for the office and reimbursement." (*Id.* at 4566.) Many of the documents, however, simply show a focus on selling the economics of the drug. A 2000 call note candidly explains, "[w]e talked to him about Taxol and the profitability spread." (*Id.* at 5895.) In other 2000 call notes, sales representatives were focusing specifically on explaining to physicians how Taxol would still be profitable after the entrance of generics in 2001. One sales representative wrote:

> We discussed the financial impact of generic competition. I explained it as the greatest business opportunity for him in many years because for every dollar BMSO lost due to price reductions needed to stay competitive with generic competition, medical ocologists [sic] would make 95 cents due to the wide disparity of cost vs AWP reimbursement.

(*Id.* at 8646.) Another representative documented his "very good conversation on generic paclitaxel and AWP situations." (*Id.* at 8664.)

Spread marketing continued in 2001 and 2002. In 2001, a sales representative noted that he gave a physician the taxol profitability sheet. (*Id.* at 6459.) It is likely that this referred to one of the presentations given to the sales representatives about reimbursement. (*See, e.g.*, PX 222; PX 225.) In 2002, a sales representative documented his discussion of spread during a meeting at a physician's office: "Discussed generic taxol. They do not want to switch. I told Melva that we are constantly lowering the cost of Taxol and that AWP is still strong. She will stay with OTN." (PX 4048 at 8182.)

ii. *Vepesid*

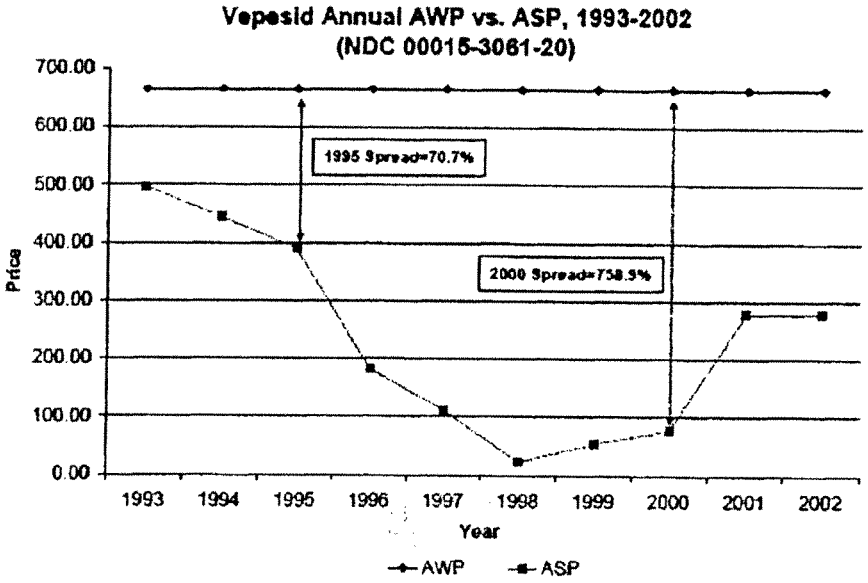
Vepesid (etoposide) is produced in an injectable form and in a capsule form. (Bell BMS Aff. ¶ 49.) The injectable form was launched in 1983 and became subject to generic competition in 1994. (*Id.* ¶ 16.) Vepesid capsules were launched in 1987 and have been subject to generic competition since 2001.(*Id.*) Vepesid is primarily used in combination with other agents for the treatment of testicular cancer and lung cancer. (Hartman Decl. ¶ 52.)

Injectable Vepesid and the capsule form had very different pricing experiences. From 1993 through 2001, BMS increased the WLP for Vepesid capsules and made further increases after the launch of generic competition in 2001. (Bell BMS Aff. ¶ 50.) For reasons which were never well explained at trial,[42] even with the advent of competition, BMS never increased price concessions more than 2 percent. (*See* Bell BMS Aff. ¶ 52.) Thus, over 90% of sales were made within 5% of list price for almost all years of the class period, including those after the entrance of generics. (*See* Bell DX 2524.) The spreads were similarly very low.

The story for the injectable form of Vepesid was much different. At the point generic competition entered the market in 1994, BMS halted all price increases and left WLP at its current level. (Bell BMS Aff. ¶ 50.) In order to protect market share, however, BMS began to offer substantial concessions to compete with the

42. Frank Pasqualone, Senior Vice President of the Oncology division at BMS, testified: "I do not recall specifically why that happened; however, in my experience there are times when generic supply becomes constrained and we are, therefore, able to make non-contract (spot) sales at higher transaction prices." (Pasqualone Aff. ¶ 41.)

generics on price. Contract discounts to large purchasers were as high as 94% off of WLP. (*See, e.g.*, PX 204 at 6293, PX 205; PX 206 at 9756, PX 207 at 4141.) For some NDCs the spread between ASP and AWP became astronomically high, exceeding 1000%. (*See* Hartman Decl. Attach. G.2.c.) Given those brand loyal and ignorant customers, however, BMS still made at least 10% of their Vepesid sales within 5% of the unchanged WLP. (*See* DX 2524.) Excluding the year 2000, however, virtually all the remaining sales were made at prices that were 50% or less of WLP. (*See id.*) Spreads thus reached over 1,000% percent. (*See* Hartman Decl. Attach. G.2.c.)



(Hartman Decl. ¶ 52, Fig. 8.)

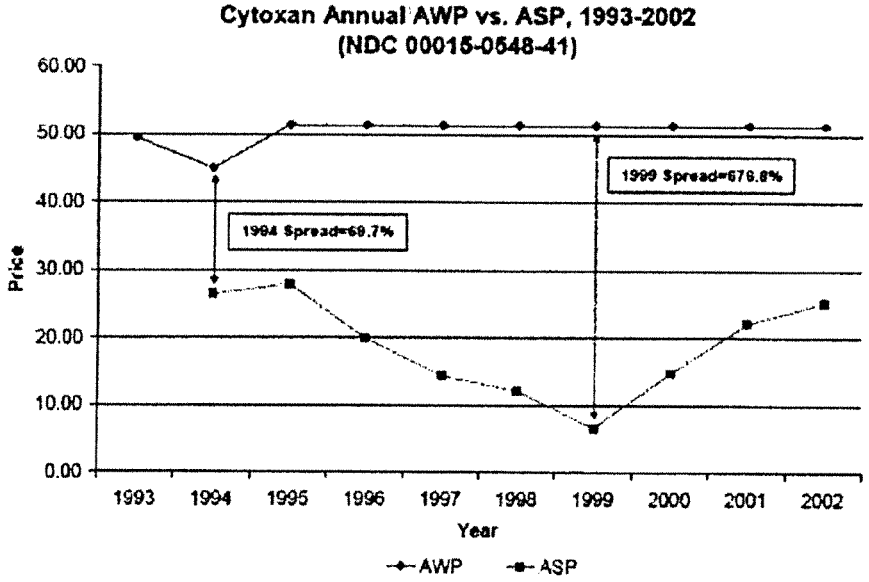
Aside from the "Cost Differential Report" available to customers online, (*see* PX 219), plaintiffs presented no further evidence that BMS proactively marketed the spread on either form of Vepesid.

iii. *Cytoxan*

Cytoxan (cyclophosphamide) is also produced in two forms, injectable and tablet. The injectable form of Cytoxan was originally approved in 1959 and has been subject to generic competition since 1982, before the start of the class period. (Bell ¶ 17.) Cytoxan tablets were approved prior to 1982 and have been subject to generic competition since 2000.(*Id.*) Cytoxan is often used in the treatment of breast cancer and non-Hodgkin's lymphoma, typically in combination with other oncolytics. (*Id.*) The pricing trajectory for the two versions of Cytoxan are similar to those of the two forms of Vepesid.

The Cytoxan tablets were relatively unaffected by generic competition. BMS increased the WLP for the Cytoxan tablets from 1993 up until the launch of generic competition in 2000. (Bell BMS Aff. ¶¶ 53–54.) From that point forward, BMS stabilized the WLP. (*Id.*) Despite the entry of generics, BMS offered less than 2% in price concessions, such that the spreads remained relatively low and the overwhelming majority of sales were made within 5% of WLP. (*See* Hartman Decl. Attach. G.2.c; DX 2524.)

Pricing for the injectable Cytoxan, however, was marked by substantial discounting and dramatic increases in the spread. While BMS kept the WLP relatively constant, contract discounts reached 65%–75% off of WLP. (*See* PX 204 at 6293; PX 205; PX 207.) This resulted in several spreads of over 100%, even reaching 500% in certain years. (*See* Hartman Decl. Attach. G.2.c.) From 1995 on, the majority of sales were made at prices less than 50% of WLP, and in certain years, as little as 6% of Cytoxan sales were made within 5% of WLP. (DX 2524.) BMS did reduce discounting somewhat from 2000–2002 because generic manufacturers were having difficulty producing the drug, and were starting to exit the market. (Rosenthal Decl. ¶ 55; Marré Dep. 88–90.) In fact, by 2003 all competitors had abandoned the market. (Marré Dep. 88:16–89:6.)



(Hartman Decl. ¶ 50, Fig. 6.)

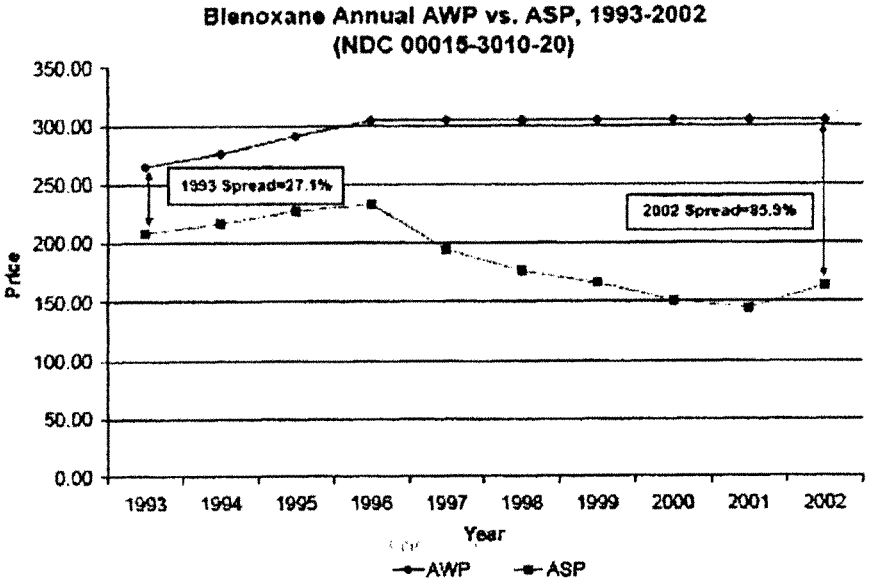
Aside from the "Cost Differential Report" available to customers online, (*see* PX 219), plaintiffs presented no further evidence that BMS marketed the spread on either form of Cytoxan.

iv. *Blenoxane*

Blenoxane (bleomycin) is a chemotherapy drug used to treat cancer including lymphomas and testicular cancers. (Hartman Decl. ¶ 46.) Blenoxane was launched in 1973 and became subject to generic competition in 1996. (Bell BMS Aff. ¶ 18.)

Like most of its other drugs, BMS increased the WLP during the period of exclusivity and then held it constant once Blenoxane faced generic competition. (*See* Hartman Decl. ¶ 47, Fig. 4.) Up until 1996, price concessions were small and the spread was therefore under 30%. (*See id.*; Bell BMS Aff. Exh. D.) In 1996, anticipating the entry of generics, BMS adjusted its pricing strategy. According to Dr. Bell, BMS attempted to get its top clients to commit to purchasing most of their bleomycin from BMS, and BMS would in return price Blenoxane competitively with any "bona fide offer for a generic." (Bell BMS Aff. ¶ 56.) Thus, discounts quickly reached over 60% off of WLP, causing the ASP to drop and the spread to reach over

100% for certain NDCs. (*See* Hartman Decl. ¶ 47, Attach. G.2.c.) In the post-generic years, only 6% to 15% of Blenoxane's sales continued to be made within 5% of WLP. (*See* Bell BMS Aff. Exh. E.)



(Hartman Decl. ¶ 47, Fig. 4.)

Aside from the "Cost Differential Report" available to customers online, (*see* PX 219), plaintiffs presented no further evidence that BMS marketed the spread on Blenoxane.

c. *Multi-Source Drugs*

i. *Rubex*

Rubex (doxorubicin hydrochloride) is used to treat a broad variety of cancers, often in combination with other therapies. (Bell BMS Aff. ¶ 19.) Rubex, a multi-source drug for the entire class period, was launched by BMS in 1989 as a branded version of Adriamycin RDF. (*Id.*) During 1992 and 1993, Rubex was marketed by Immunex Corporation, but reverted back to BMS in 1994.(*Id.*) BMS phased out the drug in 2001 and discontinued production after 2002. (Marré Dep. 97:22–98:12.)

Since Rubex is a multi-source drug, BMS has always offered substantial concessions off of the WLP. While the WLP remained fairly constant, discounts have averaged as high as 94% off of WLP. (*See* Bell BMS Aff. Exh. D.) Thus, the spreads were large, peaking at over 400% toward the end of the 1990's. (*See* Hartman Decl. Attach. G.2.c.) On average, 37% of the Rubex sales were made at list price, although that percentage ranged from 0% to 62% throughout the individual years. (DX 2524.)